



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/867,034 | 05/29/2001 | Roberto A. Macina | DEX-0207 | 5629 |
| 26259 | 7590 | 08/31/2004 | EXAMINER | |
| LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053 | | | YU, MISOOK | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/867,034 | Applicant(s) MACINA ET AL. | |
| | Examiner MISOOK YU, Ph.D. | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's submission of new CRF and sequence listing filed on 6/17/04 are acknowledged.

Claims 1 and 15 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The amendment filed 6/17/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the specification as originally filed does not have SEQ ID NO:26. It is noted that the instant specification claims priority benefit to the US Provisional application 60/207,383. Anything that is supported by the instant application as originally filed and also supported by the priority document will be given the filing date of the priority document. However, the disclosure not supported by the instant application as originally filed could be not added during the prosecution based on the disclosure of the priority document. Applicant did not incorporate the priority document in its entirety.

Applicant is required to cancel the new matter in the reply to this Office Action.

Art Unit: 1642

Claim Rejections - 35 USC § 112, Maintained

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:5, does not reasonably provide enablement for any other polynucleotide with 97% identity to SEQ ID NO:5.

Claim 1 is interpreted as drawn to nucleic acid with 97 % identity to SEQ ID NO:5. Applicant argues one of skill in the art would know how to make and use such sequences. The argument has been fully considered but found unpersuasive because the specification does not teach how to use a polynucleotide with 97 % identity to SEQ ID NO:5. The specification teaches that SEQ ID NO:5 is overexpressed in colon cancer. The specification at page 86 teaches that instant SEQ ID NO:5 is overexpressed in colon cancer samples as compared to normal colon tissue. The specification does not teach which 97 % of instant SEQ ID NO:5 must be conserved in order to be overexpressed in colon cancer tissue. Therefore, it is concluded that the specification does not teach how to make polynucleotide with 97 % identity to SEQ ID NO:5.

Claim 1 remains rejected and claim 15 is newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the specification has been amended to include more nucleic acid that meets the structural limitation of claim 1. However, as stated above,

Art Unit: 1642

the introduction of the new sequence is new matter. Further, there is a lack of written description for polynucleotides comprising SEQ ID NO:5 and polynucleotide with 97% identity to SEQ ID NO:5.

It appears that SEQ ID NO:5 is a partial cDNA. The specification does not teach what the claimed polynucleotide encodes for or where in the structure a open reading frame start and end. The specification teaches at page 86 that SEQ ID NO:5 is overexpressed in colon cancer. The instant claims are drawn to a genus of polynucleotide that minimally contains SEQ ID NO:5 or polynucleotide with 97% identity to SEQ ID NO:5. The present claims encompasses full-length gene(s) and cDNAs that are not further described in the instant specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Weighing all factors, 1) partial structure of the DNA that comprises SEQ ID NO:5 or comprises DNA, or 97% identity to SEQ ID NO:5, 2) the breadth of the claims as

Art Unit: 1642

reading on genes and naturally occurring variants yet to be discovered, 3) the lack of correlation between the structure and the function of the gene(s), one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNA which comprises SEQ ID NO:5.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

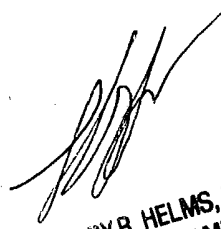
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER